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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,721

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Richard Martin

EXS-402US

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

10/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/506,721	<b>Applicant(s)</b> MARTIN ET AL.	
	<b>Examiner</b> TAMTHOM N. TRUONG	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 8-6-08 (Election).
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 22, 25, 27, 28, 31, 33, 34, 36, 37, 39-42, 45, 46, 48, 99 and 100 is/are rejected.
- 7) ☒ Claim(s) 5, 7, 10, 11, 30, 43, 49, 50, 101 and 103-105 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                    |                                                                                         |
|--------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                               | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>NONE</u> . | 6) <input type="checkbox"/> Other: _____                                                |

Continuation of Disposition of Claims: Claims pending in the application are 1-7,10,11,15-22,25-28,30,31,33,34,36,37,39-43,45,46,48-50,53-56,58,59,61,62,64,65,67-69,71,72,74-76,78,80,81,83-101 and 103-105.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 15-21,26,53-56,58,59,61,62,64,65,67-69,71,72,74-76,78,80,81 and 83-98.

### DETAILED ACTION

In the reply of 8-6-08, applicant's election with traverse of group I is acknowledged. The traversal is on the ground that several claims are generic or linking claims, and thus, non-elected portion should be examined also. The traversal is not found persuasive. Although linking claims are generic, they are drawn to different formulae. Furthermore, applicants present 105 claims, and thus, together with non-elected formulae, it would impose a serious burden of searching and examination on the examiner. It is recognized that the claims are written in Markush format. For a Markush group to be proper, it must (1) share a common utility, and (2) share a “**substantial structural feature**” essential to that utility. In the instant case, the Markush of formula I has quinazolinone ring which is not a substantial structural feature. It is the combination of the quinazolinone ring together with  $R^1$ - $R^6$  that determine the feature essential to a method of treating various disorders. Thus, the Markush group is improper because it lacks a “substantial structural feature”.

Applicant inquired about the status of claims 84-98 and 104. Claims 84-98 are listed in Group IV, and claim 104 should be in Group I. For the record, the groups are reiterated as below:

**Group I:** claim(s) 1-7, 10, 11, 22, 25, 27-31, 33, 34, 36, 37, 39-43, 45, 46, 48-51, 99-101, and 103-105 drawn to compounds of **formula III** which is a subgenus of formula I wherein:

- $R^1$  is an optionally substituted phenyl group;
- One of  $R^4$  and  $R^5$  is  $-S(O)_jR^{11}$ ;
- Wherein  $j = 2$ , and  $R^{11}$  is an optionally substituted aryl group;
- Two of  $R^{1a}$  or  $R^3$  do **not** form a ring.

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And pharmaceutical composition thereof; classified in class 514, subclass 266.3, and class 544, subclass 287.

**Group II:** claim(s) 1, 2, 15-22, 25-31, 33, 34, 36, 37, 39, 53-56, 58, 59, 61, 62, 64, 65, 67-69, 71, 72, 74, 75, 76, 78, 99 and 100, drawn to compounds of **formula V** which is a subgenus of formula I wherein:

- $R^1$  is an optionally substituted phenyl group;
- One of  $R^4$  and  $R^5$  is  $-C(E)R^{23}$ ;
- Wherein E is oxygen and  $R^{23}$  is an optionally substituted aryl group.
- Two of  $R^{1a}$  or  $R^3$  do **not** form a ring;

And pharmaceutical composition thereof; classified in class 514, subclass 266.3, and class 544, subclass 287.

**Group III:** claim(s) 1, 2, 5, 7, 10, 11, 22, 25-31, 33, 34, 36, 37, 39, 80, 81, 83, 99, 100 and 101, drawn to the remaining compounds of formula I which are not in the above groups (e.g., those with  $R^1$  as an optionally substituted alkyl, alkenyl, alkynyl group, etc.), classified in classes 514 and 544, various subclasses. Further restriction and/or election of species will be required if this group is elected.

**Group IV:** claim(s) 84-98, drawn to a method of treating, preventing or ameliorating the symptoms of several diseases using a compound of formula I, classified in classes 514 and 544, various subclasses. Further restriction and/or election of species will be required if this group is elected.

Claims 8, 9, 12-14, 23, 24, 29, 32, 35, 38, 44, 47, 51, 52, 57, 60, 63, 66, 70, 73,

77, 79, 82 and 102 are cancelled.

Claims 1-7, 10, 11, 15-22, 25-28, 30, 31, 33, 34, 36, 37, 39-43, 45, 46, 48-50, 53,

54-56, 58, 59, 61, 62, 64, 65, 67-69, 71, 72, 74-76, 78, 80, 81, 83-101, 103-105 are

pending.

**Non-elected subject matter:** Claims 15-21, 26, 53-56, 58, 59, 61, 62, 64, 65, 67-69, 71, 72, 74-76, 78, 80, 81 and 83-98 are withdrawn as being drawn to the non-elected subject matter.

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Claims 1-7, 10, 11, 22, 25, 27, 28, 30, 31, 33, 34, 36, 37, 39-43, 45, 46, 48-50, 99-101, 103 and 104 are remained for consideration.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3, 6, 22, 25, 27, 28, 31, 33, 34, 36, 37, 39-41, 99 and 100 are rejected under 35 U.S.C. 102(b) as being anticipated by **Rao et. al.** On page 234, compound 6 reads on the instant formula I or III with the following substituents:

- i.  $R^1$  (of formula I) is phenyl;  $n = 1$ ;  $R^{1a}$  is alkyl (or  $CH_3$ );
- ii.  $m = 2$ ;  $R^3$  is halogen;
- iii.  $R^2$  and  $R^6$  are hydrogen;
- iv.  $R^4$  is hydrogen;
- v.  $R^5$  (of formula I) is  $-SO_2$ Phenyl;
- vi.  $t = 1$ ,  $R^{5a}$  is  $-NR^{24}COR^{26}$ .

The disclosed compound has antifungal activity, and thus, inherently anticipate the instant pharmaceutical composition claims as well.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-4, 22, 25, 27, 28, 31, 33, 34, 36, 40, 41, 42, 45, 46, 48, 99 and 100 are rejected under 35 U.S.C. 102(e) as being anticipated by **Baxter et. al.** (US 6,545,005 B1).

In columns 75 & 76, compound #14 reads on the instant formula I or III with the following substituents:

- i.  $R^1$  (of formula I) is phenyl;
- ii.  $n = 1$ ;  $R^{1a}$  is halogen;
- iii. One of  $R^2$  and  $R^6$  is hydrogen, and the other is an alkyl group;
- iv.  $m = 0$ ;  $R^3$  does not exist;
- v.  $R^4$  is an alkyl group (or  $CH_3$ )

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vi.  $R^5$  (of formula I) is  $-\text{SO}_2\text{phenyl}$ ;

vii.  $T = 1$ ;  $R^{5a}$  is a haloalkyl group (or  $\text{CF}_3$ )

The disclosed compound can antagonize "hedgehog" signaling pathway, and thus, anticipate the instant pharmaceutical composition claims as well.

### *Claim Objections*

3. Claims 5, 7, 10, 11, 30, 43, 49, 50, 101, 103, 104 and 105 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The above claims recite a subgenus or species having a combination of substituents that are not taught or fairly suggested by the prior art of record.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAMTHOM N. TRUONG whose telephone number is (571)272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tamthom N. Truong/

**/James O. Wilson/  
Supervisory Patent Examiner, Art Unit 1624**

***Tamthom N. Truong  
Examiner  
Art Unit 1624***

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9-25-08